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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS-NOP-12-0016; NOP-12-07FR]

RIN 0581-AD27

National Organic Program (NOP); Amendments to the National List of Allowed and Prohibited Substances (Crops and Processing).

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule amends the U.S. Department of Agriculture's (USDA's) National List of Allowed and Prohibited Substances (National List) to enact five recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB) on November 5, 2009, and December 2, 2011. This final rule amends the exemptions (uses) for one substance, peracetic acid, for organic crop production. This final rule also amends the exemptions for three substances used in organic handling: potassium hydroxide, silicon dioxide, and beta-carotene extract color. This final rule also removes the allowance for nonorganic annatto extract color from the National List for organic handling.

DATES: This rule is effective [INSERT DATE 1 DAY AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], except for the amendment in instruction 4 to "silicon dioxide" in § 205.605(b) and the amendment in instruction 6 to, § 205.606(d), which are effective November 3, 2013. For more information on these effective dates, see **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Melissa Bailey, Ph.D., Director, Standards Division, National Organic Program, Telephone: (202) 720-3252; Fax: (202) 205-7808.

SUPPLEMENTARY INFORMATION:

I. Background.

On December 21, 2000, the Secretary established within the National Organic Program (NOP) (7 CFR part 205) the National List regulations sections 205.600 through 205.607. The National List identifies the synthetic substances that may be used and the nonsynthetic (natural) substances that may not be used in organic production. The National List also identifies nonsynthetic nonagricultural, synthetic nonagricultural, and nonorganic agricultural substances that may be used in organic handling. The Organic Foods Production Act of 1990 (OFPA), as amended (7 U.S.C. 6501-6522), and USDA organic regulations, in section 205.105, specifically prohibit the use of any synthetic substance in organic production and handling unless the synthetic substance is on the National List. Section 205.105 also requires that any nonorganic agricultural and any nonsynthetic nonagricultural substance used in organic handling must also be on the National List.

Under the authority of the OFPA, the National List can be amended by the Secretary based on recommendations developed by the NOSB. Since established, AMS has published multiple amendments to the National List beginning on October 31, 2003 (68 FR 61987). AMS published the most recent amendment to the National List on September 27, 2012 (77 FR 59287).

This final rule amends the National List to enact five recommendations submitted to the Secretary by the NOSB on November 5, 2009, and December 2, 2011.

II. Overview of Amendments

The following provides an overview of the amendments made to designated sections of the National List regulations:

Section 205.601 Synthetic Substances Allowed for Use in Organic Crop Production

This final rule amends subparagraphs (a)(6) and (i)(8) of section 205.601 by amending two listings for peracetic acid to read as follows:

(a)(6) Peracetic acid—for use in disinfecting equipment, seed, and asexually propagated planting material. Also permitted in hydrogen peroxide formulations as allowed in § 205.601(a) at concentration of no more than 6% as indicated on the pesticide product label.

(i)(8) Peracetic acid—for use to control fire blight bacteria. Also permitted in hydrogen peroxide formulations as allowed in § 205.601(i) at concentration of no more than 6% as indicated on the pesticide product label.

After consideration of the comments received, AMS determined that the substance’s use annotation should be modified from the proposed rule. This final rule differs from the text originally proposed as follows for paragraph (a)(6) (emphasis added): “Also permitted in hydrogen peroxide formulations as allowed in § 205.601(a) at concentration of no more than 6% as indicated on the pesticide product label.” Similarly, the use annotation for paragraph (i)(8) was modified as follows: “Also permitted in hydrogen peroxide formulations as allowed in § 205.601(i) at concentration of no more than 6% as indicated on the pesticide product label.” Additional explanation for the modification is provided in the **COMMENTS RECEIVED** section of this rule.

Section 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food groups(s)).”

This final rule amends paragraph (b) of section 205.605 of the National List regulations by amending the annotations for potassium hydroxide and silicon dioxide to read as follows:

Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches.

Silicon dioxide—Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available.

Section 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

This final rule amends section 205.606 of the National List regulations by amending paragraph (d)(3) to read as follows:

Beta-carotene extract color—derived from carrots or algae (pigment CAS# 7235-40-7). This final rule also removes annatto extract color from paragraph (d)(1) and redesignates paragraphs (d)(2) through (d)(19) as paragraphs (d)(1) through (d)(18).

III. Related Documents.

Two notices were published regarding meetings of the NOSB and its deliberations on recommendations and substances petitioned for amending the National List. Substances and recommendations addressed by this final rule were announced for NOSB deliberation in the following Federal Register notices: (1) 74 FR 46411, September 9, 2009 (peracetic acid); and (2) 76 FR 62336, October 17, 2011 (potassium hydroxide, silicon dioxide, beta-carotene extract color, and annatto extract color). The proposal to amend the annotation for four substances in this final rule, along with the removal of one substance, was published as a proposed rule in the Federal Register on February 5, 2013 (78 FR 8040).

IV. Statutory and Regulatory Authority

The OFPA, as amended (7 U.S.C. 6501-6522), authorizes the Secretary to make amendments to the National List based on proposed amendments developed by the NOSB. Sections 6518(k)(2) and 6518(n) of the OFPA authorize the NOSB to develop proposed amendments to the National List for submission to the Secretary and establish a petition process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion or deletion from the National List. The National List petition process is implemented under section 205.607 of the USDA organic regulations. The current petition process (72 FR 2167, January 18, 2007) can be accessed through the NOP Web site at <http://www.ams.usda.gov/nop>.

A. Executive Order 12866

This action has been determined not significant for purposes of Executive Order 12866, and therefore, has not been reviewed by the Office of Management and Budget (OMB).

B. Executive Order 12988

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This final rule is not intended to have a retroactive effect.

States and local jurisdictions are preempted under the OFPA from creating programs of accreditation for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to USDA to be accredited as a certifying agent, as described in section 6514(b) of the OFPA. States are also preempted under section 6503 through 6507 of the OFPA from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to section 6507(b)(2) of the OFPA, a State organic certification program may contain additional requirements for the production and handling of organically produced agricultural products that are produced in the State and for the certification of organic farm and handling operations located within the State under certain circumstances. Such additional requirements must: (a) Further the purposes of the OFPA, (b) not be inconsistent with the OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

Pursuant to section 6519(f) of the OFPA, this final rule would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601-624), the Poultry Products Inspection Act (21 U.S.C. 451-471), or the Egg Products Inspection Act (21 U.S.C. 1031-1056), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301-399), nor the authority of the Administrator of the Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136-136(y)).

Section 6520 of the OFPA provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. The OFPA also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's final decision.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would

accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose is to fit regulatory actions to the scale of businesses subject to the action. Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

Small agricultural service firms, which include producers, handlers, and accredited certifying agents, have been defined by the Small Business Administration (SBA) (13 CFR 121.201) as those having annual receipts of less than \$7,000,000 and small agricultural producers are defined as those having annual receipts of less than \$750,000.

U.S. sales of organic food and non-food have grown from \$1 billion in 1990 to \$31.4 billion in 2011. Sales in 2011 represented 9.5 percent growth over 2010 sales.¹ According to USDA, National Agricultural Statistics Service (NASS), certified organic acreage exceeded 3.5 million acres in 2011.² According to NOP's Accreditation and International Activities Division, the number of certified organic operations in the U.S. has more than doubled over time from approximately 7,000 operations in 2000 to over 17,000 operations by the end of 2011. Of these operations, over 4,900 are organic handlers, over 10,000 are organic crop producers, and over 1,900 are organic livestock producers. AMS believes that most of these entities would be considered small entities under the criteria established by the SBA.

In addition, the USDA has 84 accredited certifying agents who provide certification services to producers and handlers. A complete list of names and addresses of accredited certifying agents may be found on the AMS NOP Web site, at <http://www.ams.usda.gov/nop>.

¹ Organic Trade Association. 2012. Organic Industry Survey. www.ota.com.

² U.S. Department of Agriculture, National Agricultural Statistics Service. October 2012. 2011 Certified Organic Productions Survey. <http://usda01.library.cornell.edu/usda/current/OrganicProduction/OrganicProduction-10-04-2012.pdf>.

AMS believes that most of these accredited certifying agents would be considered small entities under the criteria established by the SBA.

AMS considered the economic impact of this action on small entities. The effect of this final rule would be to expand the allowed uses of peracetic acid in organic crop production. AMS concluded that expanding the allowance for peracetic acid on the National List both addresses EPA relabeling issues for products used in organic crop production and enables organic producers to continue using a substance for sanitation and plant disease control on organic farms. Therefore, this action will be beneficial to small agricultural service firms. This final rule also expands the use of potassium hydroxide and beta-carotene extract color in organic handling. AMS concluded that expanding the allowance for these substances on the National List provides organic handlers with more tools for processing organic products and, therefore, will be beneficial to small agricultural service firms. This final rule amends the allowance for synthetic silicon dioxide such that organic rice hulls would be required as an alternative to silicon dioxide when commercially available. The rule continues to allow the use of synthetic silicon dioxide as a defoamer. The rule also allows the continued use of synthetic silicon dioxide when organic rice hulls are not available in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic handling. This flexibility is intended to minimize the impact on small entities by allowing synthetic silicon dioxide if organic rice hulls are not commercially available, while still meeting the requirement under section 205.600(b)(1) that synthetic substances can be used only when there are no organic substitutes. This final rule also removes the allowance for one nonorganic agricultural substance, annatto extract color, in organic handling. The NOSB has determined that annatto extract color is commercially available in organic form in sufficient quantities for organic handling. AMS concluded that the

economic impact of this amendment to the National List, if any, would be minimal to small agricultural service firms and may spur further development of organic annatto production.

Accordingly, AMS certifies that this rule will not have a significant economic impact on a substantial number of small entities.

D. Paperwork Reduction Act

No additional collection or recordkeeping requirements are imposed on the public by this final rule. Accordingly, OMB clearance is not required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, Chapter 35.

E. Executive Order 13175

This final rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

F. Comments Received on Proposed Rule AMS-NOP-12-0016; NOP-12-07PR

AMS received 43 comments on the proposed rule AMS-NOP-12-0016; NOP-12-07PR. Comments were received from organic producers and handlers, manufacturers of peracetic acid and silicon dioxide products, a nonprofit organization, an industry group, specialty food ingredient processors and distributors, specialty food products manufacturers, three trade associations, accredited certifying agents, an organic consultant, and private citizens.

Most comments favored amending the National List with the changes described in the proposed rule. Four comments stated general opposition to the allowance of any substance on the National List, but did not provide specific comments on the proposed amendments. Comments received for each substance are further described below. One comment opposed the use of

genetically modified organisms (GMOs), which is outside the scope of this rulemaking action and is already prohibited under the USDA organic regulations at section 205.105(e).

Comments on the proposed amendment for beta-carotene extract color and removal of annatto extract color were supportive of the actions as proposed. Therefore, AMS is finalizing the amendment and removal of these substances, respectively, as proposed through this final rule.

Changes Based on Comments

Peracetic Acid

AMS received 24 comments regarding the proposed change to peracetic acid. Most comments supported a continued allowance for peracetic acid in organic crop production. A few comments indicated that peracetic acid should not be allowed, but did not provide information on alternative practices or other materials that are available as alternatives to its use.

The majority of commenters requested that AMS revise the proposed annotation for peracetic acid to include the word “also” at the beginning of the second sentence, and to cite the listings for hydrogen peroxide at sections (a)(4) and (i)(5). This amendment was suggested to clarify that peracetic acid in hydrogen peroxide formulas at concentrations less than the stated percentage will not be subject to the peracetic acid use restrictions. AMS agrees and has accepted this change, with modification. AMS has included the word “also” and the paragraphs letters that were requested, i.e., (a) and (i). AMS did not include the subsequent number in paragraph letter (i.e., (a)(6) or (i)(8)) in order to avoid the need to renumber these listings if substances are added or removed from paragraphs (a) or (i) of section 205.601 at a later date.

In the proposed rule, AMS specifically requested comments that identified any formulated hydrogen peroxide products labeled for agricultural use that contain more than 5% peracetic acid and that may be impacted by the rulemaking action. Three comments addressed

this topic. AMS received one comment from an organic mushroom producer that uses a formulated product that contains 5.6% peracetic acid. AMS also received two comments from chemical suppliers that requested that the percentage of peracetic acid be raised to 6% and 17%. In reviewing the comments, AMS considered the intent of the NOSB recommendation to restrict the amount of peracetic acid by annotation to only allow hydrogen peroxide products that contain a small amount of peracetic acid and that are subject to new labeling requirements under EPA. The intent of the NOSB was not to allow organic peroxide products containing high levels of peracetic acid up to 17%. After consideration of the comments, AMS has amended the annotation for the final rule to increase the percentage of peracetic acid included in the annotation from 5% to 6% as indicated on the pesticide product label. AMS has increased this percentage up to 6% to ensure that the formulated products currently used in the marketplace would continue to be allowed in organic production.

Implementation Periods

In the proposed rule, AMS requested comments that described whether product reformulation will be necessary and the timeframe that will be needed to comply with the proposed amendment for silicon dioxide at section 205.605(b) and the proposed removal of annatto extract color from section 205.606.

AMS received seven comments regarding the timeframe that organic handlers need to implement the amendment to silicon dioxide, ranging from immediately to four years. Two commenters requested an effective date of two years. One commenter requested 3-4 years, and another requested 4-6 months. One distributor of organic rice bran products in the EU did not suggest a specific timeframe, but noted that in general, its customers who use organic rice hulls as a replacement for silicon dioxide are rather quick to implement this change. The commenter

noted that adjustment may be needed to find the right replacement amount, since it may vary from application to application. One commenter indicated that they use rice hulls as a flavor carrier and anti-caking agent and indicated that they were able to implement this ingredient substitution within a few weeks. Another commenter indicated their initial substitution trials for replacing silicon dioxide with organic rice concentrate took several months to collect and approve all data and update packaging. This handler now uses the rice substitute product in all new product development, and as such, and did not request additional time for implementation. After considering the comments received, AMS has established an effective date of November 3, 2013, for this action to ensure that industry is provided advanced notification of the change to the listing for silicon dioxide. In addition, based on comments that some product testing and reformulation will be needed, AMS considers a one year period from the effective date (i.e., until November 3, 2014) as reasonable and appropriate for the industry to reformulate products. This implementation period is intended to ensure that the amendment is effectively and rationally implemented by allowing time for handlers to test organic rice hulls as a replacement for silicon dioxide, and to allow for reformulation and label changes, if needed. AMS will be conducting outreach to the industry and training for certifying agents as appropriate.

AMS received two comments addressing the time needed to implement the removal of annatto extract color from the National List. One commenter suggested 24 months from the date the final rule is released; the other suggested a minimum of two years. In consideration of the comments, AMS has established an effective date of November 3, 2013 for this removal. Further, AMS considers a one year period from the effective date (i.e., until November 3, 2014) as reasonable and appropriate for the industry to comply with this final rule. This implementation period is intended to ensure that the amendment is effectively and rationally implemented by

allowing time for handlers to source organic annatto extract and to allow for ingredient substitution and label changes, if needed. AMS will be conducting outreach to the industry and training for certifying agents as appropriate.

Changes Requested But Not Made

Peracetic Acid

One commenter indicated that it is not clear why peracetic acid should be allowed, but did not provide information on the availability of alternative practices or materials. AMS received many comments from certified organic growers indicating the need for this substance; therefore, this material should continue to be permitted in organic crop production.

One commenter supported the proposed action, but indicated that limiting the allowance of peracetic acid to fire blight is not expansive enough, and that it should be allowed without any restriction. An expanded allowance for peracetic acid was requested in the petition considered by the NOSB.³ The expanded allowance requested was not recommended by the NOSB due to concerns over the impact of broad spectrum use on soil microbes. Upon review, AMS concurs with the NOSB recommendation and has not accepted the commenter's suggestion for an expanded use.⁴

One commenter supported the proposed action and proposed language that would add “must be followed by a fresh water rinse” to the text of the annotations for peracetic acid at paragraphs (a)(6) and (a)(8) of 205.601. However, no rationale for this addition was provided. We have not accepted this suggestion. This substance is used in organic crop production as sanitizer and fungicide and there is no requirement on the label for a freshwater rinse. Further,

³ The petition for peracetic acid is available on the NOP Web site at <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5071775&acct=nopgeninfo>.

⁴ NOSB Final Recommendation on Peracetic Acid (Expanded Use). November 2009. Available in Petitioned Substances Database under “P,” at the NOP Web site: <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5067081&acct=nopgeninfo>.

the added process of a freshwater rinse could diminish the effectiveness of the substance for its intended use.

One commenter indicated that AMS should not restrict the percentage and use of peracetic acid, as the higher the percentage of peracetic acid, the less costly it is to use for a farmer that needs the substance in volume. In this action, AMS has retained a stated percentage of peracetic acid in the rule, in an effort to maintain the intent of the NOSB's recommendation to continue to allow hydrogen peroxide products that contain a small amount of peracetic acid. The allowance of higher concentrations of peracetic acid for control of fire blight and for use in disinfecting equipment, seed, and asexually propagated planting material are not impacted by this action.

Potassium hydroxide

AMS received eight comments regarding the proposed change to potassium hydroxide. Some commenters supported the change as proposed. Some commenters opposed any expansion of the use of this substance in organic handling, but did not include data on available alternative materials or practices for peeling peaches.

One commenter indicated that the allowance for potassium hydroxide should not be expanded since this material is toxic to human health and that its use has adverse effects on the environment. The commenter also noted that potassium hydroxide is not allowed in organic handling in the European Union or by the International Federation of Organic Agriculture Movements (IFOAM) standards. AMS has considered the comment, as well as the status of potassium hydroxide under the regulatory authority of the Food and Drug Administration (FDA). According to FDA, potassium hydroxide is generally recognized as safe (GRAS) when used as a formulation aid, a pH control agent, a processing aid or a stabilizer and thickener (21 CFR 184.1631). The FDA regulations further provide that substances generally regarded as safe in

food may be used to wash or to assist in the peeling of fruits and vegetables (21 CFR 173.315). As such, AMS agrees with the NOSB recommendation that the annotation for potassium hydroxide should be revised to allow its use in any peach processing (e.g., frozen, canned), as there are no commercially viable alternatives for peeling peaches. In comparison to the previous allowance for this substance to peel peaches that would be individually quick frozen, there is no additional risk to the human health or the environment by expanding the allowance of potassium hydroxide for peeling peaches for other types of processing (e.g., canning). Therefore, AMS has adopted the proposed annotation for potassium hydroxide as final rule without change.

The same commenter indicated that they did not support the proposed rule because they believe there is a conflict of interest, suggesting that a contributor to the 2001 technical advisory panel (TAP) that informed the Board's recommendation on this substance worked on the petition related to the same substance ten years later in 2011. AMS does not agree that this is a conflict of interest. In its deliberations, the NOSB considers a wide range of information to make a recommendation on a particular substance. This includes the petition, any technical information such as TAPs and Technical Reports, and public comments. The comment also indicated that AMS should not implement the change for potassium hydroxide because the NOSB did not request a new technical report. However, the NOSB is not required to request a new or updated technical report for all petitioned substances. In this case, existing information was available in the form of a technical report, and the report was available on the NOP website to the NOSB and the public in advance of the public meeting at which the NOSB recommended that potassium hydroxide be allowed in any peach peeling process.⁵

⁵ Technical Report on Potassium hydroxide. May 21, 2001. Available in Petitioned Substances Database, under "P," at the NOP Web site: <http://www.ams.usda.gov/NOPPpetitionedSubstancesDatabase>.

One commenter proposed language that would add the following additional text to the proposed annotation for potassium hydroxide (emphasis added): “Potassium hydroxide – prohibited for use in lye peeling of fruits and vegetables, except when used for peeling peaches. In this instance, potassium hydroxide is to be permitted and allowed for any peach peeling in organic process, including freezing and canning processes.” No explanation was provided on the need for this additional clarification. AMS believes the text, as proposed and finalized through this rule, is adequate as the substance can be used to peel peaches, regardless of the type of processing (e.g., canned, frozen).

Silicon Dioxide

AMS received 20 comments regarding the proposed amendment to the listing for silicon dioxide. One commenter indicated that silicon dioxide should not be allowed in any organic foods, but did not provide information on availability of alternative practices or materials.

Several comments from organic handling operations indicated that AMS should not adopt the proposed rule, since organic rice hulls do not adequately substitute for silicon dioxide in all applications, and that that organic rice hulls may substitute for the use of silicon dioxide only in limited circumstances. Commenters indicated that rice hulls do not function as a one-for-one replacement for silicon dioxide, and that substitution may compromise quality, appearance, and stability of organic products or ingredients. Commenters also indicated that silicon dioxide is widely used in many food and beverage applications, including, dried fruit and vegetable powders, ground chili products, fish oil, soup powders, sugars, cake mixes, non-dairy creamers, salt, spices, hot chocolate, and many yeast/flour-based powdered mixes. Other commenters who supported the rule indicated that organic rice hulls were able to substitute for silicon dioxide in their applications.

AMS believes the rule, as proposed and as adopted as final rule through this action, provides the flexibility that is needed by organic handlers. As indicated in the proposed rule, the annotation for silicon dioxide allows for the continued use of silicon dioxide in handling applications if organic rice hulls do not adequately substitute for the functionality provided by silicon dioxide. The term “commercially available” is defined under section 205.2 of the USDA organic regulations as “the ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan.” Linking the use of silicon dioxide by annotation to the commercial availability of organic rice hulls reflects the NOSB’s intent to permit the use of synthetic silicon dioxide when organic rice hulls do not fulfill an essential function in a system of organic handling, as determined by the certifying agent in the course of reviewing the organic plan. Inclusion of the commercial availability clause for organic rice hulls in the annotation provides the flexibility that was intended by the NOSB and does not exclude handlers from using silicon dioxide or other organic products in those applications where organic rice hulls do not provide the functionality needed. The annotation requires handlers to use organic rice hulls in place of silicon dioxide when it is available to substitute for synthetic silicon dioxide. In addition, the rule provides flexibility for handlers by allowing the continued use of silicon dioxide in those applications where organic rice hulls do not provide the functionality needed (e.g., as a defoamer). This rule implements the intent of the NOSB to limit the allowance of silicon dioxide to those functions where it is essential for the handling of organically produced agricultural products, as required by section 205.600(b)(6).

One commenter indicated concerns regarding the exclusive acceptability of organic rice hulls as the only acceptable anticaking agent because it may not perform in the applications in

which silicon dioxide has been proven effective. AMS disagrees with this interpretation. The rule does not restrict the use of other organic ingredients as a substitute for silicon dioxide in organic product formulation. Instead, the rule implements a requirement that an organic alternative must be used in place of a synthetic substance on the National List when the organic alternative is commercially available.

One commenter suggested text to replace “organic rice hulls” with “non-synthetic alternatives.” As indicated in the proposed rule, AMS has specified the one particular nonsynthetic alternative (i.e., organic rice hulls) that was evaluated by the NOSB within the annotation so that certifying agents can consistently verify that organic handlers are in compliance with the regulations. The clarification also reduces the burden on organic handlers since they would not be required to demonstrate that all nonsynthetic alternatives to synthetic silicon dioxide were considered prior to its use.

One commenter indicated that commercial availability should not apply to section 205.605 of the National List and that applying the rule to silicon dioxide would not be consistent with other materials on the list. AMS disagrees, as the listing for yeast on section 205.605(a) of the National List includes a clause regarding commercial availability. In addition, the NOSB recommendation to include commercial availability within the annotation for silicon dioxide was drafted after significant public comment to address the concerns from organic handlers that the alternative organic rice product may not function as a substitute for silicon dioxide in all applications. AMS concurs with the NOSB’s justification for inclusion of this text regarding commercial availability; therefore, we have not accepted the suggestion of the commenter to remove this text.

One commenter was concerned about the effect of the allowance of silicon dioxide in downstream products for companies that purchase ingredients that contain silicon dioxide, and the number of downstream products that may need to be reformulated based on this action. This commenter also indicated that their operation has conducted significant amounts of research and development in the past to find a way to incorporate rice hulls into their products as a viable substitute for silicon dioxide. The commenter indicated that organic rice hulls do not perform like silicon dioxide and that rice hulls do not serve the required purpose within the type of organic products that they produce. As previously stated, the new annotation would allow the continued use of silicon dioxide when organic rice hulls are not commercially available to perform an essential function in organic handling.

One commenter did not support the rule, but indicated that, if implemented, AMS should modify the proposed annotation as follows (emphasis added): “Silicon dioxide – Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available or do not function adequately in the product application.” AMS believes that the annotation adopted in this final rule provides the flexibility that is intended by the commenter’s suggestion. The definition of “commercially available” under section 205.2 already includes the ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling. We find the phrases “fulfill an essential function” and “function adequately” to be equivalent; therefore, the suggested text has not been adopted.

One commenter noted that there are various forms of silicon dioxide, including precipitated silica, fumed silicas, aerogels, naturally occurring silicas, and mined mineral silicas. The commenter indicated that AMS should reach out to other industry groups and document other various silica types currently approved for use in the organic industry before a decision to

eliminate one silica dioxide form. AMS understands that there may be multiple types of silicon dioxide in use in organic products, as the regulations do not specify Chemical Abstracts Service (CAS) numbers for different forms of silicon dioxide on the National List. As this action does not restrict the forms of synthetic silicon dioxide that are permitted for use, we have not accepted the suggestion of the commenter on this issue.

One commenter indicated that they support the use of agricultural products as a replacement for silicon dioxide, but expressed concerns about the levels of arsenic in rice products. The commenter indicated that additional testing and review should be required prior to its approval and implementation. The commenter cited data published in November 2012 by Consumer Reports of arsenic levels in rice products.⁶ Under section 205.602(b) of the USDA organic regulations, the use of arsenic is prohibited in the production of organic crops, including rice. AMS understands that as a result of the study cited by the commenter, the US Food and Drug Administration (FDA) is currently investigating arsenic levels in foods.⁷ As all food must comply with FDA food safety requirements, AMS did not adopt the suggestion of the commenter to require additional testing and review of organic rice hulls used in organic products prior to implementation of this rule.

One commenter proposed language that would add the following additional text to the proposed annotation for silicon dioxide: “In food products, concentration limited to 5mg per serving.” We have not accepted the suggestion of the commenter as no explanation was provided on the need for this limitation.

⁶ “Arsenic in Your Food,” Consumer Reports Magazine, November 2012. Available at <http://www.consumerreports.org/cro/magazine/2012/11/arsenic-in-your-food/index.htm>

⁷ Questions & Answers: FDA’s Analysis of Arsenic in Rice and Rice Products; available at <http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm319948.htm>

Two commenters noted that the proposed text did not specify that the use of organic rice hulls is only required in products making an “organic claim,” and recommended that the annotation be amended since commercial availability does not apply to products in the “made with organic (specified ingredients or food group(s))” labeling category. AMS has not adopted this suggestion. As specified under section 205.600, synthetic substances are evaluated under the criteria specified by OFPA; in addition, processing aids and adjuvants are evaluated against additional criteria, including the availability of organic alternatives. OFPA and the USDA organic regulations do not include separate criteria for evaluation of synthetic substances used in the different labeling categories. As explained in the proposed rule, AMS specified in the annotation that the rice hulls must be organic, since the use of conventional (i.e., nonorganic) rice and rice products is not permitted in products labeled as “organic” under the USDA organic regulations. Organic or nonorganic rice hulls would be permitted as a substitute for silicon dioxide in a “made with organic (specified ingredients or food group(s))” product under section 205.301(c) of the USDA organic regulations.

One commenter, who supported the proposed action, expressed concern regarding certifying agents that may permit an overly liberal reading of the commercial availability clause. AMS believes the existing accreditation requirements for certifying agents are sufficient for NOP to address any compliance issues with certifying agents who are not adequately implementing the USDA organic regulations, including annotations for substances on the National List.

G. Effective Date

This final rule reflects recommendations submitted to the Secretary by the NOSB. The substances being amended or removed from on the National List were based upon petitions from the industry and were evaluated by the NOSB using criteria in the OFPA and the USDA organic

regulations. Because these substances have been subject to such extensive discussion and comment, AMS believes that producers should be able to use the expanded allowances for peracetic acid, potassium hydroxide, and beta-carotene extract color in their operations as soon as possible. Further, the harvest season for organic peaches will begin in June; without this final action, potassium hydroxide can only be used to peel peaches for frozen product. This final rule will enable organic peach producers to commercially process and market canned organic peaches. It is also important for AMS to expeditiously address EPA relabeling issues for hydrogen peroxide products used in organic crop production, and this will be achieved by finalizing the amendment to peracetic acid. Accordingly, AMS finds good cause exists under 5 U.S.C. 553(d)(3) for not postponing the effective date of this rule for these three substances until 30 days after publication in the Federal Register.

As discussed above in Section F, the effective date for the new annotation for silicon dioxide and for removal of annatto extract color is established as November 3, 2013.

List of Subjects in 7 CFR part 205

Administrative practice and procedure, Agriculture, Animals, Archives and records, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, 7 CFR part 205, subpart G, is amended as follows:

PART 205—NATIONAL ORGANIC PROGRAM

1. The authority citation for 7 CFR part 205 continues to read as follows:

Authority: 7 U.S.C. 6501-6522.

2. Section 205.601 is amended by revising paragraphs (a)(6) and (i)(8) to read as follows:

§ 205.601 Synthetic substances allowed for use in organic crop production.

* * * * *

(a) * * *

(6) Peracetic acid—for use in disinfecting equipment, seed, and asexually propagated planting material. Also permitted in hydrogen peroxide formulations as allowed in § 205.601(a) at concentration of no more than 6% as indicated on the pesticide product label.

* * * * *

(i) * * *

(8) Peracetic acid—for use to control fire blight bacteria. Also permitted in hydrogen peroxide formulations as allowed in § 205.601(i) at concentration of no more than 6% as indicated on the pesticide product label.

* * * * *

3. In § 205.605, the entry for “potassium hydroxide” in paragraph (b) is revised to read as follows:

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

* * * * *

(b) * * *

Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches.

* * * * *

4. In § 205.605, effective November 3, 2013, the entry for “silicon dioxide” in paragraph (b) is revised to read as follows:

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

* * * * *

(b) * * *

Silicon dioxide—Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available.

* * * * *

5. In § 205.606, paragraph (d)(3) is revised to read as follows:

§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

* * * * *

(d) * * *

(3) Beta-carotene extract color—derived from carrots or algae (pigment CAS# 7235-40-7).

* * * * *

§ 205.606 [Amended]

6. In § 205.606, effective November 3, 2013, paragraph (d) is amended by removing paragraph (d)(1) and redesignating (d)(2) through (19) as (d)(1) through (18).

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Dated: May 21, 2013

Rex A. Barnes
Associate Administrator
Agricultural Marketing Service

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